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(54) Portable apparatus for foetal monitors

(57) A hand-held device for monitoring the cardiac rate of a foetus by ultrasonic Doppler measurement of the blood flow is adapted to measure the baseline cardiac rate and variability, the absence of decelerations and the increase following foetal "kicks". Means (9) are provided to allow the operator, e.g. the mother, to enter the occurrence of "kicks" as she feels them during the measurement. The device stores present limits for the various measurements and provides an output understandable to the motor based on the measurements. The output may be a textual or audible instruction such as when to repeat the test or whether to seek medical advice. The device includes a transducer 3, amplifier 5, microprocessor 7, LED display 13, and a speaker 17 and/or headphones and a printer.

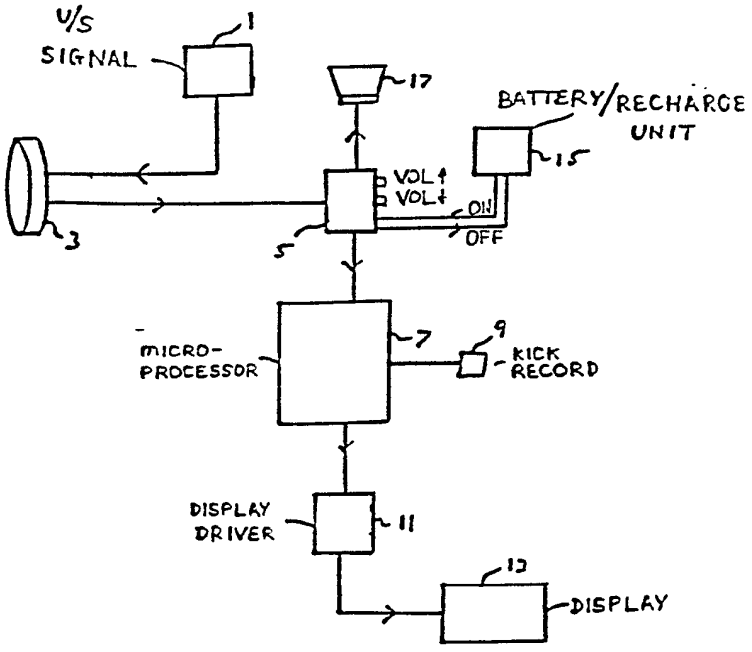

FIG 2

At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

The claims were filed later than the filing date within the period prescribed by Rule 25(1) of the Patents Rules 1982.

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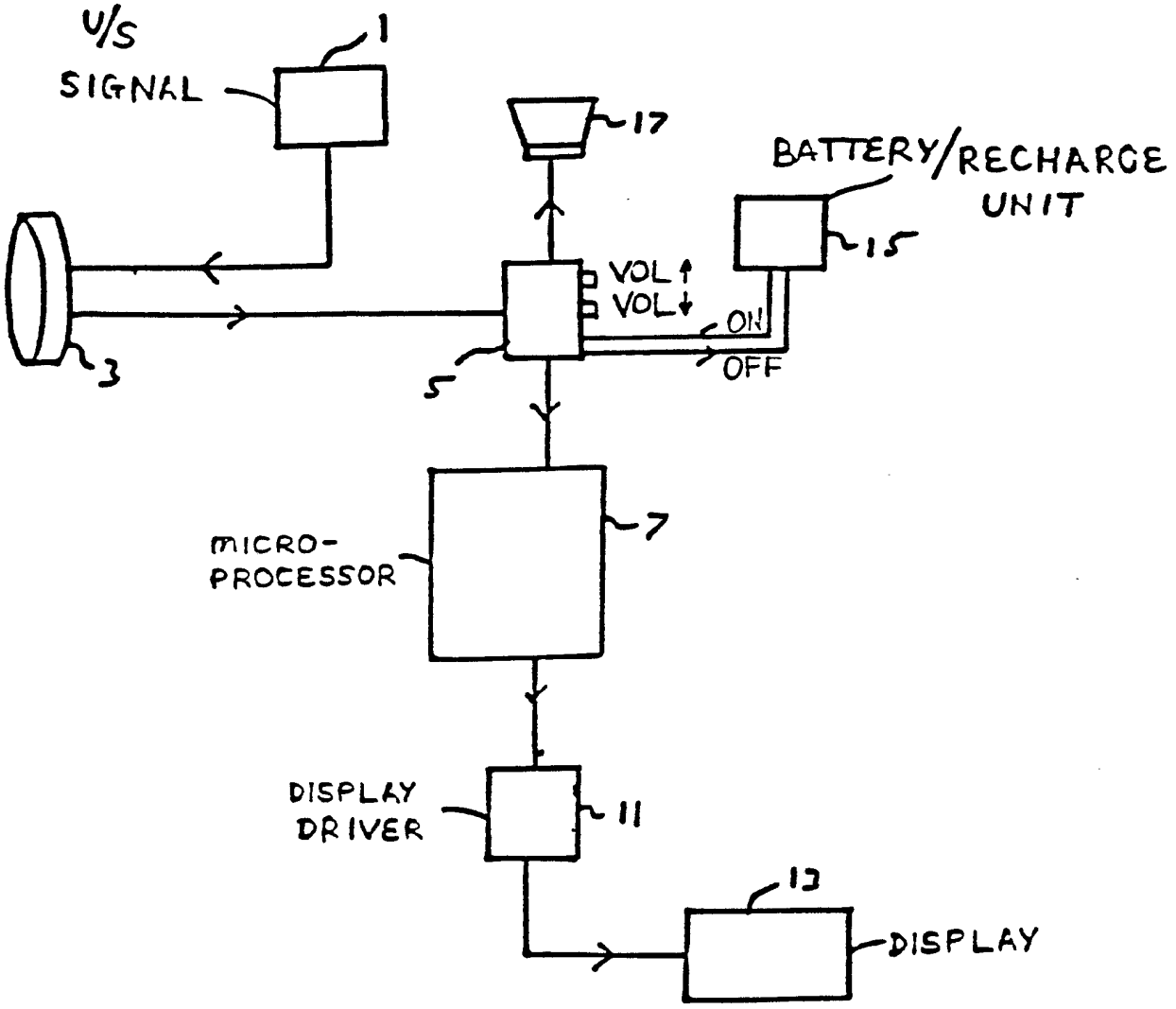
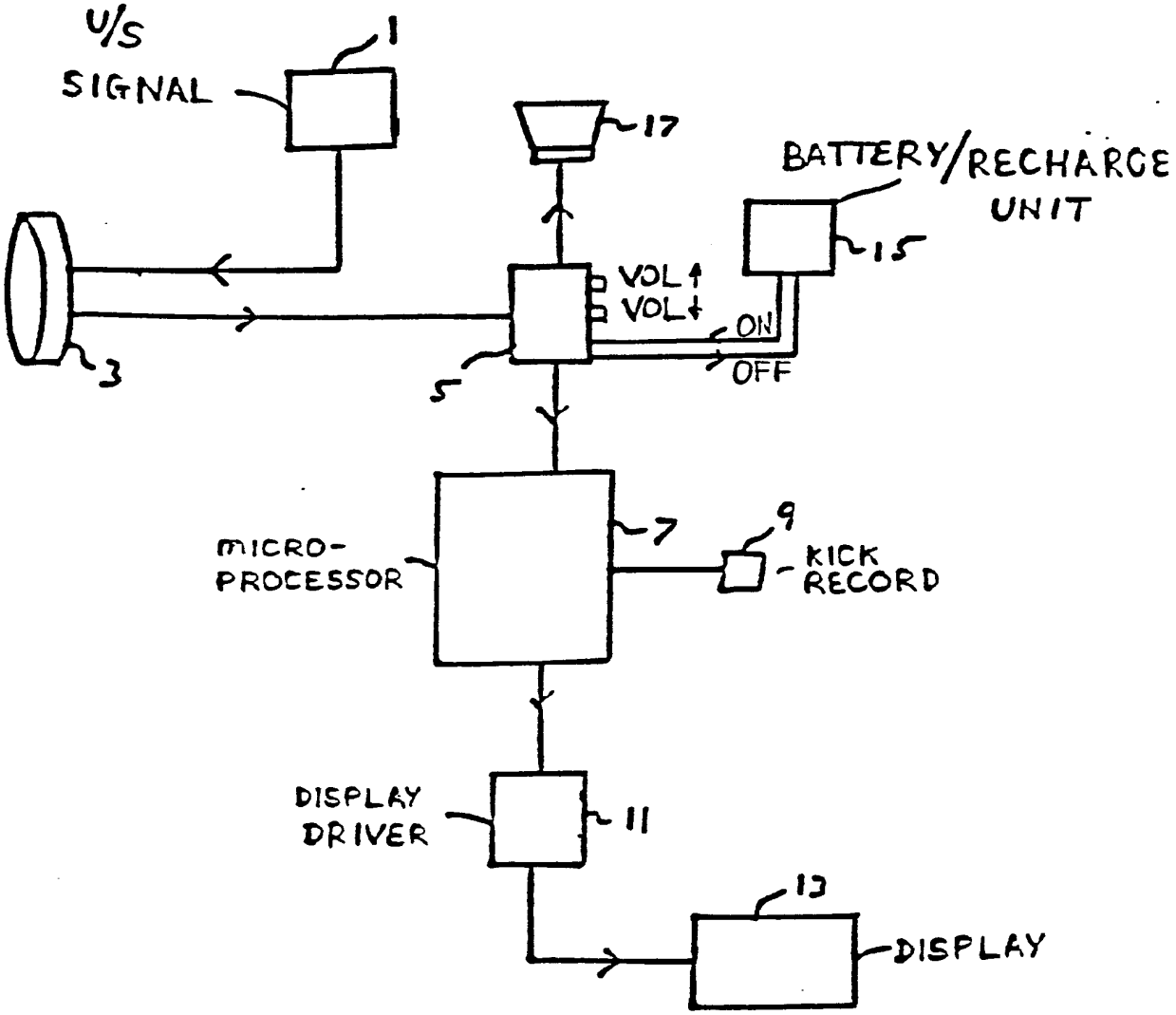

U/S
SIGNAL
1
17
BATTERY/RECHARGE
UNIT
15
VOL ↑
VOL ↓
ON
OFF
3
5
MICRO-
PROCESSOR
7
DISPLAY
DRIVER
11
13
DISPLAY

FIG 1


U/S
SIGNAL
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PROCESSOR
7
9
KICK
RECORD
DISPLAY
DRIVER
11
13
DISPLAY

FIG 2

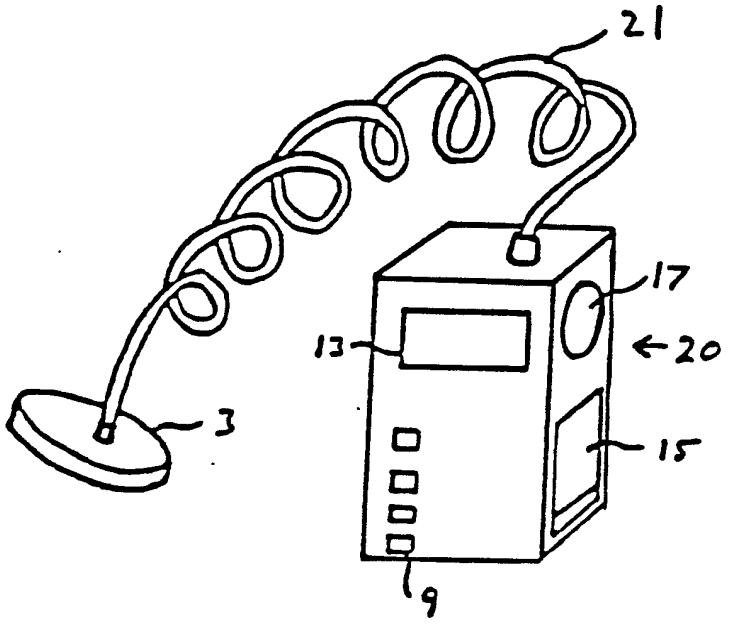

FIG. 3

"APPARATUS FOR FOETAL MONITORING"

This invention relates to apparatus for foetal monitoring and in particular to apparatus which is suitable for screening of large numbers of pregnancies.

In the past 20 years improvements in medical techniques have resulted in a reduction in the perinatal mortality rate from about 3% to the present level of about 1%. This is in part as a result of a better understanding of the causes of stillbirths, but also is as a result of the introduction and improvement of foetal monitoring techniques. However, although the monitoring techniques are thought to perform well and to be successful at detecting abnormalities in the pregnancy, it is not yet practicable for every pregnancy to be monitored at a high frequency, e.g. every day. The tests need to be carried out in a hospital or clinic and if every pregnancy were to be monitored in this way every day, there would clearly be a considerable burden on the medical authorities as well as a considerable degree of inconvenience for the patients. At present, therefore, certain tests on the foetus are carried out only once or twice during a normal pregnancy and only abnormal pregnancies are monitored more frequently. This can be carried out by monitoring of the foetal heart using Doppler techniques at the hospital. More recently systems have been developed in which real time and stored foetal

heart recordings are transmitted by the mother over the telephone so that at-risk pregnancies can be monitored without the need for daily attendance at a clinic or hospital. However, those methods require expensive equipment and also trained personnel to receive and interpret the recordings, and whilst useful for abnormal pregnancies, are hindered by cost and are inappropriate for large-scale screening. According to a first aspect the present invention provides a hand-held device for monitoring the heart rate of a foetus and providing an output indicative of the heart rate. The unit may also provide an audio output of or representative of the beat or heart rate.

Conveniently the measurement may be obtained by a Doppler measurement using an ultrasound transducer provided in the hand-held device or in a sense head connected by a flexible cable to the hand- held unit. Such a device measures the Doppler effect caused by the ultrasound waves passing through moving blood which may be in the ventricles or aorta. The known Doppler technique for blood flow monitoring may be used in which the frequency change caused by the Doppler effect is in the audible range. This audible signal may be amplified and emitted from a speaker provided in the device so that the heart beats can be heard. This helps in finding a sufficiently strong signal.

According to a second aspect of the present invention there is provided apparatus for monitoring the heart of a foetus and processing results and providing an

output message based thereon in a form understandable by a non-medically qualified person, e.g. the mother herself. The output may be given as an instruction to the mother. Preferably the device is compact, personally portable and simple to use so that it is suitable for use at home by the mother.

The messages may be given as simple text messages or by illumination of a light or by an audible, e.g. synthesised or recorded voice, output.

Conveniently the device includes a means for measuring the cardiac rate of the foetus and also means to allow the mother to enter the occurrence of foetal movements or "kicks" and preferably the apparatus includes a processor to process the cardiac rate measurement and "kick" indicative signal to determine whether the heart condition of the foetus is normal.

Conveniently the beat-to-beat measurement may be made by Doppler measurement using an ultrasound transducer in a similar manner to the device according to the first aspect of the invention. The apparatus may process the beat-to-beat signal to determine the baseline cardiac rate, the absence of decelerations, and the presence of accelerations in response to foetal kicks. If the measurements lie within preset normal ranges for a foetus, then an output message is displayed, preferably as a textual message, to indicate that the reading is normal and that it should be repeated at the normal interval. If, for some

reason, the reading is unsatisfactory then a message can be provided to indicate that the test should be repeated and if the measurements are outside the normal ranges, then an indication can either be given that the test should be repeated after a certain time, e.g. 2 hours, or that the mother should contact the hospital or medical authorities. The textual display can conveniently be on an LED display.

Preferably the preset normal ranges for the three measurements mentioned above are that the average baseline rate should be between 120 and 160 beats per minute, accelerations of 15 b.p.m. should follow two foetal kicks and the heart rate should not fall from the baseline rate by more than 15 b.p.m.

An additional test may also be provided in which the baseline variability of the cardiac rate is measured. This measurement is particularly appropriate in pregnancies which are in some way abnormal or thought to be at-risk.

With such an embodiment of the invention, therefore, the mother can be provided with a small hand-held, easy-to-use apparatus which she can take home from a certain time in the pregnancy, e.g. 34 weeks, and instructed to find and measure the foetal heart rate at a regualar time each day. The mother records the heart rate until two foetal kicks have occurred, the occurance of which is entered into the apparatus using a kick-record button and the recording is then discontinued. The apparatus processes the results and produces an appropriate textual message upon which the mother can act.

Thus with the invention it is possible for a large number of pregnancies to be monitored every day without the need for medical attention to the large number of so-called normal healthy cases. Only those cases in which an abnormality is detected will require attendance.

The present invention will be further described by way of non-limitative example with reference to the accompanying drawings in which:-

Figure 1 is a schematic diagram of a first embodiment of the present invention;

Figure 2 is a schematic diagram of a second embodiment of the present invention; and

Figure 3 illustrates the apparatus of Figure 2.

With the illustrated embodiment of the present invention, the health of a foetus is checked by monitoring its heart rate. The apparatus measures the cardiac rate by measuring the Doppler effect between ultrasound waves passing through blood in the heart or major blood vessels, and the heart condition can be deduced by monitoring the heart rate for a certain time. As mentioned above, the apparatus is designed to be used by the mother at home without medical supervision and is designed so that the mother need take no action involving the medical authorities as long as the heart condition is satisfactory.

Figure 1 illustrates in block diagram form a first embodiment of the invention and comprises an ultrasound signal generator 1 which, in use, supplies a signal to a

widebeam ultrasound transducer 3. The widebeam ultrasound transducer may be, for example, a Hewlett-Packard HP 8040A transducer which is sensitive and easy to use. The output of the transducer 3, which will be a signal exhibiting the Doppler effect resulting from the transmission of the sound waves through moving blood, is supplied by an interface amplifier 5 to a microprocessor 7. The output of the microprocessor 7 is transmitted via a display driver 11 to a display 13 which is, in this embodiment, an LED display capable of displaying short text messages. Provision may also be made for a hard-copy output by providing a printer in the unit and a memory device may also be provided for storing a record of the measurements. The unit is also provided with a battery or recharge unit 15 which to supply power for the device.

The unit is also provided with an audio speaker 17 to which the Doppler signal, suitably amplified by interface/amplifier 5 (which is provided with volume and on/off controls), is supplied. Headphones may be provided in addition or as an alternative. Thus the user can listen to the signal and move the transducer around until the strongest sounds of blood flow/heart beat are heard.

In this first embodiment the apparatus measures the beat-to-beat heart rate and displays the rate as a number of beats per minute on the L.E.D. display 13. It is possible for the apparatus to provide an output representative of the instantaneous rate or of the rate averaged over a period of time.

Thus the first embodiment provides a relatively cheap and easy-to-use foetal heart monitor. The apparatus is compact and so can be used away from the hospital, e.g. by midwives making home visits.

A second embodiment of the apparatus is shown in Figures 2 and 3. Figure 2 is a block diagram illustrating the apparatus and is similar to tnat of Figure 1 and like aspects are designated with like reference numerals. It will be seen that in addition to the features of the first embodiment the apparatus is provided with a kick-record button 9 which the mother or user presses when a foetal kick is felt and which provides a kick-indicative signal to the microprocessor 7. The provision of the kick signal allows the apparatus to analyse the heart rate signal in a more detailed manner than with the first embodiment and provide a more useful output. The processor 7 is arranged to analyse the signal and provide an output in the form of a textual message to the mother which instructs the mother how to proceed. This is described in more detail below.

Similarly to the first embodiment the apparatus may be provided with a printer to provide a hard-copy print-out or headphones instead of or as well as the speaker 17.

Figure 2 illustrates an example of the apparatus of Figure 1 and as can be seen most of the parts of the device are housed in a unit 21 to which the ultrasound transducer 3 is connected by a flexible cable 21. The unit 20 is small and compact so that it is personally portable. The flexible

cable 21 is of such a length that the transducer 3 may be moved around on the mother's abdomen to detect the foetal heart rate while the unit 20 is held in a comfortable position.

In this embodiment the apparatus measures the beat-to-beat heart rate and compares certain aspects of that rate to preset values to deduce whether the heart rate is normal or abnormal. The heart condition can be deduced from three aspects of the measured heart rate, namely:

1. The average baseline cardiac rate;

2. The absence of decelerations in the cardiac rate; and

3. The presence of acelerations in the cardiac rate in response to foetal kicks indicated by generation of the kick record button.

In a healthy foetus the baseline cardiac rate would be between 120 and 160 beats per minute and will not decelerate to any great extent, e.g. in this embodiment by more than 15 b.p.m. Furthermore, when the foetus kicks, the heart rate should increase, and a normal acceleration is 15 b.p.m., twice following kicks. In this embodiment the basic cardiac rate information is measured using the Doppler monitor and information on the kicks is supplied by the mother via the kick record button 9. It is intended that the mother should be instructed to record the heart rate until two foetal kicks have been recorded. This measurement should be repeated at a similar time each day during the later stages of pregnancy.

This embodiment of the invention is intended to be used by a mother at home, and so it is not desirable to output the results of the measurements as numerical information of the type required by a doctor. Instead the measurements are processed and the output is presented as a simple instruction in a textual message. In this embodiment four textual messages are used:

1. NORMAL - REPEAT TOMORROW
2. a. INADEQUATE - REPEAT NOW
   b. REPEAT LATER TODAY
3. HEART RATE FAST 190 RING HOSPITAL
4. UNREACTIVE RING HOSPITAL

The message giving heart rate faster than usual will be given if the heart rate is greater than 160 beats per minute. The normal heart record signal will be given if the average baseline rate is between 120 and 160 beats per minute with accelerations of 15 b.p.m. twice following kicks and if the heart rate does not fall from the baseline rate by more than 15 b.p.m. The other messages will be given depending on how far the measurements lie outside the present normal ranges and the inadequate text message if, for instance, the signal received was noisy or not performed for long enough.

The mother is therefore told whether the test is normal and she should simply repeat it on the next day or

whether for some reason, e.g. because the transducer was placed wrongly, the test was unsatisfactory, or whether because of a slight, but not serious, abnormality the test should be repeated later or whether she should ring the hospital because one or other of the measurements fell outside the accepted ranges.

The messages can, however, be worded differently or in other languages as necessary.

Thus once provided with the foetal monitor, the mother need only contact the medical authorities if the foetal heart rate is abnormal in some way. This means that a large number of pregnancies can be screened without there being an undue burden on the medical authorities caused by the need to deal with the majority of healthy normal pregnancies. In addition, the apparatus can be used in women who have been identified as "at risk".

In an alternative embodiment of the invention the microprocessor 7 also measures the baseline variability of the cardiac rate which is a useful additional test. The use of this test is particularly important if the apparatus is used to monitor pregnancies which are in some way "at risk".

The procedure which it is contemplated would be adopted for use of the apparatus in screening pregnancies is as follows. At present, in most hospitals in the UK, women are asked to record their baby's foetal movements daily from 34 weeks gestation until delivery. With the present invention it is possible to contemplate that women would be

loaned a personal monitor to take home from 34 weeks and given instructions on its use by the medical staff or midwife. Each day at home at a convenient time (for example between 9 a.m. and 4 p.m.) they will locate and record the foetal heart rate until two foetal kicks have been detected. The occurrence of kicks is entered in the device by pressing the "kick" button. The recording is then discontinued and the apparatus will analyse the rate, decelerations, and accelerations. Based on the results the LED display will give one of the preprogrammed instructions. If the results are abnormal or suspicious then the mother is instructed to contact the hospital or clinic, otherwise to repeat the test as normal the next day or sooner for an inadequate test. It has been found in home monitoring studies using other apparatus that the quality of recordings obtained by the patient is generally superior to those obtained by the midwife. Since the invention is relatively cheap and fairly easy to manufacture, it allows a screening system to be operated in which all pregnancies are screened. This is a considerably improvement on the present system where only pregnancies which are thought to be "at risk" are monitored daily.

CLAIMS

1. A portable device for measuring the heart rate of a foetus comprising a sensor for detecting the heart beat of the foetus and processing means for processing the sensor output and providing an output message indicative of the heart rate, the device being so constructed and dimensioned to allow hand-held operation thereof.

2. A device according to claim 1 wherein the output message is in a form understandable to a non-medically qualified person.

3. A device for monitoring the heart rate of a foetus comprising a sensor for detecting the heart beat of the foetus and providing a sensor output indicative thereof, processing means for processing the sensor output and for providing an output message based thereon in a form understandable to a non-medically qualified person and means for outputting the message.

4. A device according to claim 3 so constructed and dimensioned to allow hand-held operation.

5. A device according to claim 1, 2, 3 or 4 wherein said processing means is adapted to derive from the sensor output the cardiac beat-to-beat time interval and to determine from that the baseline cardiac rate.

6. A device according to claim 5 wherein

said processing means is adapted to detect decelerations in the baseline cardiac rate and compare them to a preset deceleration limit and to generate said output message dependent on its relation to that limit.

7. A device acccording to claim 6 wherein the deceleration limit is decelerations of approximately 15 bpm.

8. A device according to claim 5, 6 or 7 wherein the processing means is further adapted to monitor the baseline variability of the cardiac rate, to compare it to preset variability limits and to generate said output message dependent on its relation to those limits.

9. A device according to claim 8 wherein the variability limits are at 120 bpm and 160 bpm.

10. A device according to any one of claims 5 to 9 further comprising recording means for recording the occurrence of foetal "kicks" and wherein said processing means monitors the acceleration of the cardiac rate following at least one "kick" and compares it to a preset value and generates said output message dependent on its relation to that value.

11. A device according to claim 10 wherein the value is an increase of 15bpm following two "kicks".

12. A device according to claim 10 or 11 wherein said recording means comprise means for allowing the mother to enter the occurrence of a foetal "kick" when

she feels the foetal "kick".

13. A device according to any one of the preceding claims wherein the output message is a textual message.

14. A device according to any one of claims 1 to 12 wherein the output message is an audible voice output message.

15. A device according to claim 13 or 14 wherein the output message is selected from one of a number of stored instructions based on one or more of the measured characteristics of the foetal heart rate.

16. A device according to claim 15 wherein the messages are selected from two or more of the following:

a) a message indicating the measurements are normal;

b) a message indicating when the next measurement should be made;

c) a message requiring immediate repeat of the measurement;

d) a message indicating that non-urgent medical advice should be sought;

e) a message indicating that urgent medical advice is required;

f) a message indicating equipment failure.

17. A device according to any one of claims 1

to 16 wherein the output message is by illumination of an indicator light.

18. A device constructed and arranged to operate substantially as hereinbefore described with reference to and as illustrated in the accompanying drawings.

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